Applicants: Nawaz Ahmad et al.

Serial No.: 10/696,939

Art Unit: 1796

Filed:

October 30, 2003

Examiner: Edw

Edward Cain

For:

WARMING AND NONIRRITATING LUBRICANT COMPOSITIONS

AND METHOD OF COMPARING IRRITATION

I hereby certify that this Submission Under 37 C.F.R. §1.99 and documents cited therein are being transmitted via The Office electronic filing system in accordance with 37 CFR 1.6(a)(4)

November 15, 2007 (Date of Transmission)

 $Karin\ L.\ Williams,\ Reg.\ No.\ 36,721$ (Name of applicant, assignee, Registered Representative, or 3^{rd} Party)

/Karin L. Williams/ (Signature)

November 15, 2007 (Date of Signature)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Nawaz Ahmad et al.

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WARMING AND NONIRRITATING LUBRICANT COMPOSITIONS

AND METHOD OF COMPARING IRRITATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUBMISSION UNDER 37 C.F.R. § 1.99

Sir:

In accordance with the provisions of 37 C.F.R. § 1.99, submitted herewith are publications that are relevant to the above-captioned pending patent application, which was published on July 15, 2004 as U.S. Patent Application Publication No. 2004/0138074 A1. Specifically, submitted herewith are copies of PAIR publications of documents from related copending Application Nos. 10/390,511 and 10/697,353.

As required by 37 C.F.R. § 1.99 and M.P.E.P. § 1134.01, the undersigned hereby:

(1) states that since (i) Amendment filed by Applicants in the above-captioned application on October 30, 2007 "change[d] the scope of the claims to an extent that could not reasonably have been anticipated by a person reviewing the published application during the period specified in 37 CFR 1.99(e)" (M.P.E.P. 1134.01(II)); and/or (ii) all of the currently submitted documents were published after the period specified in 37 C.F.R. § 1.99(e) expired, the publications could not have been submitted to the Office earlier, within two months of the July 15, 2004 publication date of the subject application;

- (2) authorizes payment of the \$130.00 processing fee set forth in 37 C.F.R. § 1.17(i) to Deposit Account 50-1047;
- (3) authorizes payment of the \$180.00 fee set forth in 37 C.F.R. § 1.17(p)) to Deposit Account 50-1047;
 - (4) lists nine publications submitted herewith:
- (i) July 26, 2006 non-final Office Action in Application No. 10/390,511 (rejecting claims 20-24, 26-33 and 35 under 35 U.S.C. § 103(a) over JP 2-311408 in view of U.S. Patent Nos. 4,232,003 and 5,512,289)
- (ii) December 22, 2006 Amendment in response to the July 26, 2006 Office $Action \ in \ Application \ No. \ 10/390, 511$
- (iii) April 2, 2007 final Office Action in Application No. 10/390,511 (rejecting claims 20-24, 26, 28-33, 35 and 36 under 35 U.S.C. § 103(a) over JP 2-311408 in view of U.S. Patent Nos. 4,232,003 and 5,512,289)
- (iv) August 2, 2007 Amendment in response to the April 2, 2007 Office Action in Application No. 10/390,511
 - (v) October 12, 2007 Restriction Requirement in Application No. 10/390,511
- (vi) November 5, 2007 Response to Restriction Requirement in Application No. 10/390,511
- (vii) March 20, 2007 final Office Action in Application No. 10/697,353 (rejecting claims 20-23 and 26 under 35 U.S.C. 102(b), or in the alternative under 35 U.S.C. § 103(a), over the English language translation of JP 2-311408 or the English language translation of JP 2001-335429 or the English language translation of ES 2,074,030 or the English language abstract of

WO 01/64176)

- (viii) October 9, 2007 Notice of Abandonment in Application No. 10/697,353
- (ix) English language translation of JP 2-3114081
- (5) submits copies of nine documents listed above in accordance with 37 C.F.R. § 1.99(d):
- (6) since all of the submitted publications are in English, no translations are required; and
- (7) certifies that the information being submitted has been served in accordance 37 C.F.R. § 1.248 on the applicant's attorney at Johnson & Johnso

In view of the above, it is respectfully submitted that this Submission complies with both timeliness and content requirements set forth in 37 C.F.R. § 1.99. Thus, the entire Submission should be forwarded to the Examiner for consideration.

The undersigned may be reached at the below listed address.

Date: November 15, 2007 Respectfully submitted,

/Karin L. Williams/ Karin L. Williams, Reg. No. 36,721

¹ First published by the European Patent Office (EPO) on or about July 25, 2005 in European Patent Application No. 03731070.3. This document may also be retrieved via the EPO's Online Public File Inspection service at http://ofi.epoline.org.

Received By:	Date:	
Name: Title:		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Nawaz Ahmad et al.

Serial No.: 10/696,939 Art Unit: 1796

Filed: October 30, 2003 Examiner: Edward Cain

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 37 C.F.R. § 1.248 on the applicant's attorney at Johnson & Johnson, One Johnson & Johnson
 Plaza, New Brunswick, NJ 08933-7003 on November ______, 2007 by hand delivery, as shown
 by ______,
 which is acceptable as proof of service under 37 C.F.R. § 1.248(b).

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In view of the above, it is respectfully submitted that this Submission complies with both timeliness and content requirements set forth in 37 C.F.R. § 1.99. Thus, the entire Submission should be forwarded to the Examiner for consideration.

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¹ First published by the European Patent Office (EPO) on or about July 25, 2005 in European Patent Application No. 03731070.3. This document may also be retrieved via the EPO's Online Public File Inspection service at http://ofi.epoline.org.

Received By: Kin Gight	Date:	11/15/07
Name: Okim Giganti		, ,
Title: Varaleen l		



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AP	PLICATION NO.	T	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	10/390,511		03/17/2003	Nawaz Ahmad	PPC834CIP	2684
	27777	7590	07/26/2006		EXAM	INER
	PHILIP S. 3	OHNS	SON		VU, JAK	E MINH
	JOHNSON 8				ART UNIT	PAPER NUMBER
	ONE JOHNS	SON &	JOHNSON PLAZ	A.	ARTONII	PAPER NUMBER
	NEW BRUNSWICK, NJ 08933-7003			3	1618	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
·						
Office Action Summers	10/390,511	AHMAD ET AL.				
Office Action Summary	Examiner	Art Unit				
	Jake M. Vu	1618				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	correspondence address ↔				
WHICHEVER IS LONGER, FROM THE MAILING DA Extensions of time may be available under the provisions of 37 CFR 1.15 after SIX (8) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statuk.	 If NO period for reply is specified above, the maximum statutory period will apply and will assize SIX (6) MONTHS from the mailing date of this communication. Failure to reply which the set or extended period for reply will, by statuto, cause the application to become ABANDONED (35 U.S.C.§ 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any 					
Status						
1) Responsive to communication(s) filed on 11 M	ay 2006.					
2a) This action is FINAL. 2b) ☑ This	action is non-final.					
 Since this application is in condition for allowant 	ice except for formal matters, pro	secution as to the merits is				
closed in accordance with the practice under E.	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.				
Disposition of Claims						
4) Claim(s) 1-35 is/are pending in the application.		•				
4a) Of the above claim(s) 1-19,25 and 34 is/are	withdrawn from consideration.					
Claim(s) is/are allowed.		•				
6) ☐ Claim(s) <u>20-24,26-33 and 35</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examiner						
10) The drawing(s) filed on is/are; a) acce	pted or b) objected to by the E	xaminer.				
Applicant may not request that any objection to the d		• •				
Replacement drawing sheet(s) including the correction		, ,				
11) The oath or declaration is objected to by the Exa	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign p	oriority under 35 U.S.C. § 119(a)-	-(d) or (f).				
a) All b) Some * c) None of:						
 Certified copies of the priority documents 	1. Certified copies of the priority documents have been received.					
Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
dee the attached detailed Office action for a list of	* See the attached detailed Office action for a list of the certified copies not received.					
		•				
Attachment(s) 1) Notice of References Cited (PTO-892)	4) Distantes C	DTO 442)				
Notice of References Cited (P10-892) Notice of Draftsperson's Patent Drawing Review (PT0-948)	4) Linterview Summary (I Paper No(s)/Mail Date	e				
Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	 Notice of Informal Pa Other: 	tent Application (PTO-152)				
S. Patent and Trademark Office	o, L. O. O. O. O. O. O. O.					

Art Unit: 1618

DETAILED ACTION

Receipt is acknowledged of Applicant's Response to Restriction/Election

Requirement filed on 05/11/2006. Claims 1-35 are pending in the instant application.

Claims 1-19, 25 and 34 are withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of Group I (claims 20-33 and 35) in the reply filed on 05/11/2006 is acknowledged. The traversal is on the ground(s) that search of all the Groups would pose no burden upon the Office. This is not found persuasive because searching all of the claims would require searching in numerous different subclasses, as well as a different searching focus depending on whether the product or method of use are being searched. Thus, the search would pose an undue burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of the "alkylene glycol" specie in the reply filed on 05/11/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the election requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, claim 25 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 05/11/2006.

Art Unit: 1618

Double Patenting

Page 3

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a teminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-33 and 35 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 7,005,408 and 5,885,591. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patents recited a method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a composition comprising polyhydric alcohol, insulating agent such as isopropyl myristate, wherein the composition convey a feeling of warmth upon application (see US 7,005,408 at claim 2). Wherein the polyhydric is an alkylene glycol (see claim 6), such as propylene glycol

Art Unit: 1618

(see claim 7). The composition further comprises a preservative (see claim 4), a bioadhesive agent (see claim 5) and honey (see claim 1).

The patent does not recite using a gelling agent such as hydroxyethylcellulose.

AKIYAMA disclosed a lubricant composition comprised of: a polyhydric alcohol, such as propylene glycol (see pg. 4), which feels warm to the touch (see pg. 4); a gelling agent, such as carboxyvinyl polymer (see pg. 5) or hydroxyethyl cellulose (see pg. 6); a preservative, such as methyl-p-aminobenzoic acid (see pg. 8); a bioadhesive agent, such as hydroxyethyl cellulose; and an insulating agent, such as isopropyl myristate (see pg. 5).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate hydroxyethyl cellulose. The person of ordinary skill in the art would have been motivated to make those modifications, because it would give the composition the desired viscosity, and reasonably would have expected success because AKIYAMA had used this in a similar composition.

Claims 20-33 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 10/389871, 10/390511, 10/696939, 10/697353, 10/697838, 10/847082, 10/847083, and 11/299884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application recites a method of providing personal lubrication to a human's oral or vaginal mucosa during intercourse comprising applying to the oral or vaginal mucosa a composition comprising a

Art Unit: 1618

substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol (see Application 11/299884 at claim 19), where in the polyhydric alcohol is selected from the group consisting of alkylene glycol (see claim 21).

The copending claims do not recite using a gelling agent such as hydroxyethylcellulose.

AKIYAMA disclosed a lubricant composition comprised of: a polyhydric alcohol, such as propylene glycol (see pg. 4), which feels warm to the touch (see pg. 4); a gelling agent, such as carboxyvinyl polymer (see pg. 5) or hydroxyethyl cellulose (see pg. 6); a preservative, such as methyl-p-aminobenzoic acid (see pg. 8); a bioadhesive agent, such as hydroxyethyl cellulose; and an insulating agent, such as isopropyl myristate (see pg. 5).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate hydroxyethyl cellulose. The person of ordinary skill in the art would have been motivated to make those modifications, because it would give the composition the desired viscosity, and reasonably would have expected success because AKIYAMA had used this in a similar composition.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1618

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior and are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-24, 26-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over AKIYAMA et al (JP2-311408) in view of POSTHUMA (US 4,232,003) and TSENG et al (US 5,512,289).

Applicant claims are directed to a method of personal lubrication to a human's vaginal mucosa comprising applying a composition comprising: a polyhydric alcohol, such as propylene glycol; a gelling agent; a preservative; a bioadhesive agent; an insulating agent, such as isopropyl myristate.

AKIYAMA disclosed a composition comprised of: a polyhydric alcohol, such as 80% of propylene glycol (see pg. 4 and pg. 9, Working Example 5), which feels warm to the touch (see pg. 4); a gelling agent, such as carboxyvinyl polymer (see pg. 5) or 1% of hydroxyethyl cellulose (see pg. 6 and pg. 9, Working Example 5); a preservative, such as methyl-p-aminobenzoic acid (see pg. 8); a bioadhesive agent, such as hydroxyethyl cellulose; and an insulating agent, such as isopropyl myristate (see pg. 5).

Note, AKIYAMA disclosed "during massage, the force of the massage is transferred tangibly to the skin without causing excess peeling of the corneum due to friction" this would read on as a function of a lubricant

Art Unit: 1618

AKIYAMA does not disclose using lactic acid in the composition or use the composition as a vaginal lubricant.

POSTHUMA disclosed, "Typical lubricants in use today as for vaginal use...constitute common lubricants such as petrolatum jelly, propylene glycol..." (see col. 1, line 28-31) and applying the lubricant to the vaginal area (see claim 1).

TSENG disclosed a vaginal lubricant comprised of: propylene glycol and hydroxyethyl cellulose (see col. 5, line 18 and col. 6, Example 1); a preservative, such as methyl paraben; and a pH adjuster such as lactic acid (see col. 11, line 17). Additional disclosure includes: the pH should be between 3-5.5 in order to be compatible with the vaginal mucosa (see col. 5, line 15-19).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate lactic acid as a pH adjuster into AKIYAMA's composition and use AKIYAMA's composition as lubrication for the vaginal area. The person of ordinary skill in the art would have been motivated to make that modification and reasonably would have expected success because AKIYAMA's composition is comprised of mostly propylene glycol, a commonly used vaginal lubricant in the prior art. Additionally, AKIYAMA disclosed the composition could be functioned as a lubricant (see pg. 11).

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a

Art Unit: 1618

person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as viscosity and pH. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Claim 27 is free of the art of record, because the prior art does not teach using honey as an insulating agent in lubrications. However, claim 27 is dependent on rejected claims.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/390,511 Page 9

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD Art Unit 1618

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINED

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	Α	US-4,232,003	11-1980	Posthuma et al.	514/772.4
*	В	US-5,512,289	04-1996	Tseng et al.	424/426
	С	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	н	US-			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	JP 2-311408	12-1990	Japan	Akiyama et al.	A61K 7/00
	0					
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NON-PATENT DOCUMENTS

		NOISPATENT DOCUMENTS
*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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"A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

NO. 0694 P. 5

UEC 2-2 2006

Docket No. PPC-834CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ahmad et al. Serial No. : 10/390.511

Senai No. : 10/390,511 Filed : March 17, 2003

Title : WARMING AND NONIRRITATING LUBRICANT

COMPOSITIONS AND METHOD OF COMPARING IRRITATION

Art Unit : 1618

Examiner : Jake Minh Vu

I hereby certify that this encrespondence is being filled via lefontimite transmitted to the US Patent and Trademark Office at (571) 273-8300 on

December 22, 2006

Andrea L. Colby, Reg. No. 30,194 (Name of applicant, assigner, or Registered Representati

/Andrea L. Colby/

· (Signature)

December 22, 2006

Commissioner for Patents

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Sir:

P.O. Box 1450 Alexandria, VA 22313-1450

This paper is respectfully submitted in response to an Office Action of Yuly 26, 2006. It is timely filed in view of the petition for a two-month extension of time submitted concurrently herewith. Please consider the following remarks.

The Listing of Claims begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

12/27/2006 HDERESS1 00000062 100750 10390511

01 FC:1201 400.00 D 02 FC:1202 50.00 D

Listing of Claims: ·

This listing of claims will replace all prior versions, and listings, of claims in the captioned application:

- (Original) A substantially anhydrous lubricant composition comprising at least one polyhydric alcohol and a gelling agent.
- (Original) A composition according to claim 1 wherein said composition further comprises a pH adjustment agent.
- (Original) A composition according to claim 1 wherein said polyhydric alcohol is selected from the group consisting of: glycerin, alkylene glycol, polyethylene glycol and a mixture thereof.
- (Original) A composition according to claim 1 wherein said gelling agent is hydroxypropylcellulose.
- (Original) A composition according to claim 3 wherein said alkylene glycol is selected from the group consisting of: propylene glycol, butylene glycol and hexalene glycol.
- (Original) A composition according to claim 4 wherein said polyethylene glycol is selected from the group consisting of polyethylene glycol 300, polyethylene glycol 400 and a mixture thereof.
- (Original) A composition according to claim 1 wherein said gelling agent is lactic acid.
- 8. (Original) A composition according to claim 5 wherein said composition comprises from about 75% to about 99% by weight of polyhydric alcohol, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
- (Original) A composition according to claim 1 wherein said composition has a viscosity from about 1,000 cps to about 7,000 cps.
- (Original) A composition according to claim 1 wherein said composition has a viscosity from about 60,000 cps to about 500,000.
- (Original) A composition according to claim 1 which further comprises an antimicrobial agent.

- (Original) A composition according to claim 11 wherein said antimicrobial agent is an antifungal agent.
- (Original) A composition according to claim 11 wherein said antimicrobial agent is an antibacterial agent.
- 14. (Original) A composition according to claim 11 wherein said antimicrobial agent is an antiviral agent.
- (Original) A composition according to claim 1 wherein said composition further comprises a spermicide.
- 16. (Original) A composition according to claim 1 wherein said composition further comprises a local anesthetic.
- (Currently amended) A method of treating or preventing dysmenorihea comprising applying a composition according to claim 1 intravaginally.
- 18. (Original) A composition according to claim 1 wherein said composition increases in temperature upon exposure to moisture.
- (Original) A composition according to claim 7 wherein the pH of said composition is adjusted to between about 2 and about 6.
- 20. (Previously presented) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition comprising at least one polyhydric alcohol and a gelling agent, said composition conveying a feeling of warmth upon application.
- (Previously presented) A method according to claim 20 wherein said composition further comprises a preservative.
- (Previously presented) A method according to claim 20 wherein said composition further comprises a bioadhesive agent.
- (Previously presented) A method according to claim 20 wherein said polyhydric alcohol is selected from the group consisting of: glycerin, alkylene glycol, polyethylene glycol and a mixture thereof.
- 24. (Previously presented) A method according to claim 23 wherein said alkylene glycol is selected from the group consisting of: propylene glycol, butylene glycol and hexalene glycol.

- 25. (Previously presented) A method according to claim 24 wherein said polyethylene glycol is selected from the group consisting of polyethylene glycol 300, polyethylene glycol 400 and a mixture thereof.
- 26. (Previously presented) A method according to claim 20 wherein said composition further comprises an insulating agent.
- 27. (Currently amended) A method of providing personal lubrication to a human's vaginal nucosa comprising applying to the vaginal nucosa a substantially anhydrous composition comprising at least one polyhydric alcohol and a gelling agent, said composition conveying a feeling of warmth upon application wherein said composition further comprises an insulating agent, A-method-according to claim-26 wherein said insulating agent is honey.
- 28. (Previously presented) A method according to claim 20 wherein said composition comprises from about 75% to about 99% by weight of polyhydric alcohol, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
- (Previously presented) A method according to claim 20 wherein said composition has a viscosity from about 1,000 cps to about 7,000 cps.
- 30. (Previously presented) A method of providing personal lubrication to a human's oral or vaginal mucosa comprising applying to the oral or vaginal mucosa a composition comprising a substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol and a gelling agent comprising a water-soluble cellulose-derived film-forming polymer.
- (Previously presented) A method according to claim 30 wherein said water-soluble cellulose-derived film-forming polymer is a hydroxyalkylcellulose polymer.
- 32. (Previously presented) A method according to claim 31 wherein said hydroxyalkylcellulose polymer is selected from the group consisting of hydroxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.
- 33. (Previously presented) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a composition

comprising a substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol and a gelling agent selected from the group consisting of hydroxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.

- (Previously presented) A substantially anhydrous lubricant composition comprising at least one polyhydric alcohol and a gelling agent.
- 35. (Previously presented) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a composition consisting essentially of a substantially anhydrous lubricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol and a gelling agent selected from the group consisting of hydroxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.
- 36. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a composition consisting essentially of a substantially anhydrous hibricant composition which conveys a feeling of warmth upon application comprising at least one polyhydric alcohol and a gelling agent selected from the group consisting of hydroxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose and hydroxypropylmethylcellulose.

REMARKS

This paper is respectfully submitted in response to an Office Action of July 26, 2006. It is timely filed in view of the petition for a two-month extension of time submitted concurrently herewith. With this extension, the due date for responding to the Office Action is December 26, 2006. Please consider the following remarks.

Claims 1-19 were originally filed in the present application. Claim 36 is newly presented. It finds basis in the Specification in the original claims and at p.13, 1. 19-p. 14, 1. 12 and p. 16, 1. 20-25. Claim 27 has been rewritten to incorporate the subject matter of the claims from which it depends. No new matter has been added in the amendments to the claims.

The Office Action of July 26, 2006 made final the restriction requirement and the applicants' election of species. Apparently, applicants' traverse of the requirement for election was inadvertently ambiguous and had been intended to extend both to the restriction requirement and the election requirements.

The Office Action of July 26, 2006 rejected claims 20-33 and 35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patents Nos. 7,005,408 and 5,885,591. Applicants respectfully submit that U.S. Patent No. 5,885,591 relates to aqueous compositions and, therefore, is inappropriate as a cited reference hereunder. Should claims be allowed in this application, applicants will submit a terminal disclaimer in view of U.S. Patent No. 7,005,408 and, if necessary, in view of U.S. Patent No. 5,885,591, as well as over copending applications Serial Nos. 10/389,871, 10/390,511, 10/696,939, 10/697,353, 10/697838, 10/847,082, 10/847,083 and 11/299,884,

The Office Action of July 26, 2006 also cites Akiyama in connection with the foregoing double patenting rejection. Applicants will discuss Akiyama in relation to the art rejections set forth below.

The Office Action of July 26, 2006 rejected claims 20-24, 26-33 and 35 under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al...in view of Posthuma...and Tseng et al. The basis for this rejection is as follows:

AKIYAMA disclosed a composition comprised of: a polyhydric alcohol...which feels warm to the touch...; a gelling agent, such as carboxyvinyl polymer...or 1% of

hydroxyethyl cellulose...; a preservative...; a bioadhesive agent...; and an insulating agent...

POSTHUMA disclosed, "Typical lubricants in use today as for vaginal use...constitute common lubricants such as petrolatum jelly, propylene glycol..." and applying the lubricant to the vaginal area...

TSENG disclosed a vaginal lubricant comprised of: propylene glycol and hydroxyethyl cellulose...; a preservative...; and a pH adjuster...

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate lactic acid as a pH adjuster into AKIYAMA's composition and use AKIYAMA's composition as hubrication for the vaginal area. The person of ordinary skill in the art would have been motivated to make that modification and reasonably would have expected success because AKIYAMA's composition is comprised of mostly propylene glycol, a commonly used vaginal lubricant in the prior art. Additionally, AKIYAMA disclosed the composition could be functioned as a lubricant. .[Office Action, p. 7]

Applicants respectfully request reconsideration of the foregoing rejection of claims 20-24, 26-33 and 35 under 35 U.S.C. 103(a) in view of Akiyama et al., Posthuma and Tseng et al. in view of the ensuing remarks.

Akiyama et al. relates to a massage product that contains "an anionic polymer compound and a water-soluble non-ionic polymer compound...in a solvent whose main component is a polyhydric alcohol, and whexein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater." [Akiyama et al. translation, p. 2] Thus, Akiyama et al requires the presence of both an anionic polymer (such as a polyacrylic acid, carboxyethyl cellulose or carboxyvinyl polymer) [Akiyama et al., p. 5] and a water-soluble non-ionic polymer compound (which might include hydroxyethyl cellulose) [Akiyama et al., p. 6]. In fact, Akiyama et al. suggests that using an anionic polymer compound is important to the composition: "if less than 0.1 wt% is used, gel formation is poor." [Akiyama et al., p. 5] (emphasis added) Thus, Akiyama et al. requires the presence of both an anionic polymer and a water-soluble non-ionic polymer. In contrast, the compositions of applicants' invention do not contain an anionic polymer.

Applicants also respectfully submit that one of ordinary skill in the art would not have been motivated to combine Akiyama et al. with either Posthuma or Tseng et al. Both Posthuma and Tseng et al. relate to aqueous compositions and do not compensate for the

insufficiencies of Akiyama et al. in leading one of ordinary skill in the art to the compositions of applicants' invention.

Even if one were to have combined Akiyama et al. with either Posthuma or Tseng et al., one of ordinary skill in the art would not have arrived at the compositions or methods of applicants' invention as these both teach compositions containing a high percentage of water. Thus, such compositions would not achieve a warming reaction when applied to the skin.

In view of the foregoing discussion, applicants respectfully request reconsideration of the rejection under 35 U.S.C. 103(a) in view of Akiyama et al., Posthuma and Tseng et al.

In view of the foregoing discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of July 26, 2006. An early allowance is earnestly solicited. Kindly direct any questions or contacts to the undersigned.

Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby

Attorney for Applicants Reg. No. 30,194

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2792

DATE: December 22, 2006



3 MONTHS

United States Patent and Trademark Office



PAPER

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/390,511	03/17/2003	Nawaz Ahmad	PPC834CIP	2684
PHILIP S. JOHNS	SON		EXAM	INER
JOHNSON & JOH ONE JOHNSON &	& JOHNSON PLAZ	A	VU, JAKE MINH	
NEW BRUNSWI	CK, NJ 08933-7003		ART UNIT	PAPER NUMBER
			1618	
HORTENED STATUTORY PE	RIOD OF RESPONSE	MAIL DATE	Τ	
		THE DATE	DELIVERY	MODE

04/02/2007 Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.	Applicant(s)	
10/390,511	AHMAD ET AL.	
Examiner	Art Unit	
Jake M. Vu	1618	

The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

- A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION
- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- B NO period for reply is a present instance, but no units consussation of present instance in the present instance in the

ta	

- 1) Responsive to communication(s) filed on 22 December 2006.
- 2a) ☑ This action is FINAL. 2b) ☐ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
 - 4a) Of the above claim(s) 1-19,25 and 34 is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- 6) Claim(s) 20-24, 26-33,35 and 36 is/are rejected.
- 7) Claim(s) 35 and 36 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(e).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the Internetional Bureau (PCT Rule 17.2(a)).
 - * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date
- 6)
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

 5) Notice of Informal Patent Application
- 6) Other:

Application/Control Number: 10/390,511 Art Unit: 1618

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 12/22/2006. Claim 36 has been added. Claims 1-36 are pending in the instant application. Claims 1-19, 25 and 34 have been previously withdrawn from consideration.

Claim Objections

Claims 35 and 36 are objected to because of the following informalities: both claims are identical claims. Appropriate correction is required.

Double Patenting

Claims 20-24, 26-33, 35 and 36 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 7,005,408 is maintained for reasons of record in the previous office action filed on 07/26/2006.

Claims 20-24, 26-33, 35 and 36 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 5,885,591 is withdrawn in view of Applicant's argument filed on 12/22/2006.

Claims 20-24, 26-33, 35 and 36 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 10/389871, 10/390511, 10/696939, 10/697353, 10/697838, 10/847082,

Art Unit: 1618

10/847083, and 11/299884 are maintained for reasons of record in the previous office action filed on 07/26/2006.

It is acknowledged that should any claims be allowed in this application, Applicant will file terminal disclaimers in view of U.S. Patent No. 7,005,408; and Application No. 10/389871, 10/390511, 10/696939, 10/697353, 10/697838, 10/847082, 10/847083, and 11/299884.

Claim Rejections - 35 USC § 103

Claims 20-24, 26, 28-33, 35 and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over AKIYAMA et al (JP2-311408) in view of POSTHUMA (US 4,232,003) and TSENG et al (US 5,512,289) are maintained for reasons of record in the previous office action filed on 07/26/2006.

Claim 27 is free of the art of record, because the references do not teach using honey as an insulating agent.

Response to Arguments

Applicant argues that AKIYAMA requires the presence of both an anionic polymer and a water-soluble non-ionic polymer; in contrast, the compositions of Applicant's invention do not contain an anionic polymer. The Examiner finds this argument unpersuasive, because Applicant uses "comprises" in the claim language, which is open-ended language. Thus, Applicant's claims could contain anionic polymer.

Art Unit: 1618

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this instance, Applicant argues that one of ordinary skill in the art would not have been motivated to combine AKIYAMA with either POSTHUMA or TSENG since the later references relate to aqueous compositions and do not compensate for the insufficiencies of AKIYAMA in leading one of ordinary skill in the art to the compositions of Applicant's invention. The Examiner finds this argument unpersuasive, because POSTHUMA disclosed that propylene glycol, which is in the AKIYAMA reference and Applicant's claims, are common lubricant used in the vagina. While the TSENG reference disclosed that pH adjusters, such as lactic acid are commonly used to adjust the pH of lubricants. Thus, it would have been obvious to the person of ordinary skill in the art to use AKIYAMA's lubricant as a vaginal lubricant with lactic acid as a pH adjuster.

Applicant argues that even if one were to have combined AKIYAMA with either POSTHUMA or TSENG, one of ordinary skill in the art would not have arrived at the composition or methods of Applicant's invention as these both teach compositions containing a high percentage of water. Thus, such composition would not achieve a warming reaction when applied to the skin. The Examiner finds this argument unpersuasive, because the primary reference, AKIYAMA, teaches the same composition as claimed by Applicant as a lubricant for massaging. Additionally,

Art Unit: 1618

AKIYAMA disclosed the lubricant "feels warm to the touch when used because of heat from the hydration reaction with the water content of the skin" (see pg. 4). Thus, such composition does achieve a warming reaction when applied to the skin.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD-Art Unit 1618

MICHAEL G. HARTLEY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants Serial No.

Ahmad et al. : 10/390.511

Filed

March 17, 2003

Title

: WARMING AND NONIRRITATING LUBRICANT

COMPOSITIONS AND METHOD OF COMPARING IRRITATION

Art Unit

: 1618

Examiner

: Jake Minh Vu

I hereby certify that this correspondence is being filed via The Office electronic filing system in accordance with 37 CFR 1.6(a)(4) on August 2, 2007

Andrea L. Colby, Reg. No. 30,194
(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

August 2, 2007 (Date of Signature)

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Sir:

This paper is respectfully submitted in response to the Final Rejection of April 2, 2007. It is timely filed in view of the petition for a one-month extension of time submitted concurrently herewith. Applicants also respectfully submit a Request for Continued Examination concurrently herewith. Please consider the following remarks.

The Listing of Claims begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the captioned application:

Claims 1-36 (Canceled)

- 37. (New) A substantially anhydrous personal lubricant composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohol, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
- 38. (New) A substantially anhydrous personal lubricant composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
- 39. (New) A substantially anhydrous personal lubricant composition consisting essentially of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.
- (New) A composition according to claim 37 wherein said composition has a viscosity from about 1,000 cps to about 7,000 cps.
- (New) A composition according to claim 37 wherein said composition has a viscosity from about 60,000 cps to about 500,000.
- (New) A method according to claim 20 wherein said composition further comprises a preservative.
- 43. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid, said composition conveying a feeling of warmth upon application.
- 44. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition

consisting essentially of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.

- 45. (New) A substantially anhydrous personal lubricant composition consisting of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.
- 46. (New) A substantially anhydrous personal lubricant composition consisting of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof and hydroxypropylcellulose.
- (New) A composition according to claim 46 wherein said composition further comprises honey.
- (New) A composition according to claim 46 wherein said polyhydric alcohols present are propylene glycol and polyethylene glycol.
- 49. (New) A composition according to claim 48 wherein said polyhydric alcohols are present in the amount of from about 75% to about 99% by weight and said hydroxypropylcellulose is present in the amount of from about 0.1% to about 4% by weight of the composition.

REMARKS

This paper is respectfully submitted in response to the Office Action of April 2, 2007. It is timely filed in view of the petition for a one-month extension of time submitted concurrently herewith. With this extension, the due date for responding to the Office Action is August 2, 2007. Applicants also respectfully submit a Request for Continued Examination concurrently herewith. Please consider the following remarks.

Claims 1-36 have been canceled without prejudice. Claims 37-49 have been added in order to expedite prosecution herein. New claims 37-49 find basis in the original claims and in the Specification at p. 13, 1. 19-p. 14, 1. 12 and p. 16, 1. 20-25. No new matter has been added in the amendments to the claims.

In the Final Rejection of April 2, 2007, Claims 35 and 36 were objected to because of the following informalities: both claims are identical claims. As claims 35 and 36 have been canceled without prejudice, applicants respectfully submit that this objection is moot.

The Final Rejection of April 2, 2007 rejected claims 20-24, 26-33, 35 and 36 on the ground of nonstatutory obviousness-type double-patenting as being unpatentable over U.S. Patent Nos. 7,005,408. This rejection was maintained for reasons of record in the previous office action of 07/26/2006. Applicants respectfully offer that, should claims be allowed in this application, they will submit a terminal disclaimer in view of U.S. Patent No. 7,005,408 as well as Applications Nos. 10/389871, 10/390511, 10/696939, 10/697353, 10/697848, 10/847082, 10/847083, and 11/299884.

The Final Rejection of April 2, 2007 rejected claims 20-24, 26, 28-33, 35 and 36 under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al (JP2-311408) in view of Posthuma (US 4,232,003) and TSENG et al (US 5,512,289). The basis for rejection was maintained from the previous office action of July 26, 2006. The Office Action of April 2, 2007 responded to applicants' previous arguments as follows:

Applicant argues that AKIYAMA requires the presence of both an anionic polymer and a water-soluble non-ionic polymer; in contrast, the compositions of Applicant's invention do not contain an anionic polymer. The Examiner finds this argument unpersuasive, because Applicant uses "comprises" in the claim language, which is open-ended language. Thus, Applicant's claims could contain anionic polymer.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking the references individually where the rejects are boned on combinations of references...In this instance, Applicant argues that one of ordinary skill in the art would not have been motivated to combine AKIYAMA et al. with either POSTHUMA or TSENG since the later references relate to aqueous compositions and do not compensate for the insufficiencies of AKIYAMA in leading one of ordinary skill in the art to the compositions of Applicant invention. The Examiner finds this argument unpersuasive, because POSTHUMA disclosed that propylene glycol, which is in the AKIYAMA reference and applicant's claims, are common lubricant used in the vagina. While the TSENG reference disclosed that pH adjusters, such as lactic acid are commonly used to adjust the pH of lubricants. Thus, it would have been obvious to the person of ordinary skill in the art to use AKIYAMA'S lubricant as a vaginal lubricant with lactic acid as a pH adjuster.

Applicant argues that even if one were to have combined AKIYAMA with either POSTHUMA or TSENG, one of ordinary skill in the art would not have arrived at the composition or methods of Applicant's invention as these both teach compositions containing ahigh percentage of water. Thus, such composition would not achieve a warming reaction when applied to the skin. The examiner finds this argument unpersuasive, because the primary reference, AKIYAMA, teaches the same composition as claimed by Applicant as a lubricant for massaging. Additionally, AKIYAMA disclosed the lubricant "feels warm to the touch when used because of heat from the hydration reaction with the water content of the skin. Thus, such composition does achieve a warming reaction when applied to the skin. [Office Action, p. 3-5]

Applicants respectfully request reconsideration of the foregoing rejection with respect to the newly-added claims and in light of the ensuing discussion.

Applicants respectfully note that claims 20-24, 26, 28-33, 35 and 36 have been canceled without prejudice in order to expedite prosecution herein. Applicants respectfully request consideration of the newly-added claims 37-49 in light of the following remarks. Applicants respectfully submit that Akiyama et al. relates to a massage product that contains "an anionic polymer compound and a water-soluble non-ionic polymer compound...in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater." [Akiyama et al. translation, p. 2] (emphasis added) Thus, Akiyama et al requires the presence of both an anionic polymer (such as a polyacrylic acid, carboxyethyl cellulose or carboxyvinyl polymer) [Akiyama et al., p. 5] and a water-soluble non-ionic polymer compound (which might include hydroxyethyl cellulose) [Akiyama et al., p. 6]. In fact, Akiyama et al. suggests that using an

anionic polymer compound is important to the composition: "If less than 0.1 wt% is used, gel formation is poor." [Akiyama et al., p. 5] (emphasis added) Thus, Akiyama et al. requires the presence of both an anionic polymer and a water-soluble non-ionic polymer. In contrast, the compositions of applicants' invention as set forth in newly-added claims 37-49 do not contain an anionic polymer. Thus, Akiyama does not teach the same composition as those claimed by applicants and, rather, teaches away from such compositions.

Although the Office Actions have cited Posthuma for indicating that propylene glycol may be used in vaginal lubricant compositions, applicants respectfully note that Posthuma teaches that propylene glycol is *not preferred* for such usage:

Typical lubricants in use today as for vaginal use do not posses [sic] special characteristics rendering them particularly suitable for this usage, but rather constitute common lubricants such as petrolatum jelly, propylene glycol, glycerine, and methyl cellulose. These lubricants have characteristics different from those of normal mucus and consequently are less than totally satisfactory for physiclogical usage. [Posthuma, col. 1, 1. 28-35] (emphasis added)

Applicants respectfully submit that the mere mention of an ingredient in a patent or publication should to be taken in the context of such publications in order to determine what the publication would have taught one of ordinary skill in the art at the time of invention. With that consideration in mind, Posthuma clearly teaches away from utilizing propylene glycol in vaginal applications.

Likewise, Tseng et al. relates to a lubricating spermicidal composition that requires the presence of a "solubilizer" in the formulation in order "to permit the spermicide to be compatible with the water-soluble polymeric matrix." [Tseng, et al., col. 2, l. 10-11] While propylene glycol and lactic acid appear in the Tseng et al. patent, the compositions described therein must contain in addition not only a spermicide, but "ethoxylated esters or ethers, or ethoxylated fatty acid derivatives wherein the fatty acid moiety contains between 8 and 16 carbon atoms" [Tseng, et al., col. 4, l. 16-20] as well as a substantial amount of water. Thus, applicants respectfully submit that Tseng, et al., alone or in combination, would not have taught one of ordinary skill in the art toward the compositions and methods of applicants' invention.

Applicants also respectfully submit that, notwithstanding the case law noted in the Office Action with regard to consideration of the references individually, applicants are

permitted to review all references for the teachings therein in order to determine if they would have taught one of ordinary skill in the art toward the compositions and methods of applicants' invention.

In light of the foregoing remarks, applicants respectfully request consideration of newly-added claims 37-49 and reconsideration of the rejection under 35 U.S.C. §103(a). Applicants respectfully submit that the combination of Posthuma, Tseng et al. and Akiyama would not have led one of ordinary skill in the art to the compositions of applicants' invention.

Therefore, applicants respectfully request reconsideration of the rejection under 35 U.S.C. 103(a) in view of Akiyama et al., Posthuma and Tseng et al. An early allowance is earnestly solicited. Kindly direct any questions or contacts to the undersigned.

Respectfully submitted,

/Andrea L. Colby/

By:

Andrea L. Colby Attorney for Applicants Reg. No. 30,194

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-2792 DATE: August 2, 2007



UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCI United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vegaria 22313-1450

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/390,511	03/17/2003	· Nawaz Ahmad	PPC834CIP	2684
PHILIP S. JOH			. EXAM	INER
JOHNSON & J ONE JOHNSO	OHNSON N & JOHNSON PLAZA		VU, JAK	EMINH
	WICK, NJ 08933-7003		ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
		*	10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	TA11				
		Applicant(s)				
Office Action Summary	.10/390,511	AHMAD ET AL.				
l annual y	Examiner	Art Unit				
The MAILING DATE of this community is	Jake M. Vu	1618				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. -Extension to the may be available under the provisions of 37 FOR 1.13(6). In no event, however, may a reply be timely fitted distributions of the communication. -If NO period for reply is appealed assistancy period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. -If NO period for reply whigh the set or assinded period by \$1.00 period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. -Any reply received by the Office later than three months after the mailing plate of this communication, even timely illed, may reduce any						
Status						
1) Responsive to communication(s) filed on 02 Au	aust 2007					
	action is non-final.					
3) Since this application is in condition for allowand	ce except for formal matters pro	secution on to the				
closed in accordance with the practice under Ex	parte Quayle, 1935 C.D. 11, 45	i3 O G 213				
Disposition of Claims	, , , , , ,					
4) Claim(s) 37-49 is/are pending in the application.						
4a) Of the above claim(s)is/are withdrawn	from consideration					
5) Claim(s) is/are allowed.	moni consideration.	•				
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.		•				
8) Claim(s) 37-49 are subject to restriction and/or e	lection requirement					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accept	ed or b) Cobjected to by the E	vamina-				
Applicant may not request that any objection to the dra	wing(s) he held in abovenee	Camiller.				
replacement drawing sheet(s) including the correction	is required if the drawing(e) is obto	atad to Co. AT OFF A service				
11) The oath or declaration is objected to by the Exam	niner. Note the attached Office A	ction or form PTO 152				
Priority under 35 U.S.C. § 119	in the state of th	10-152.				
12) Acknowledgment is made of a claim for foreign pri	Oriby under 35 U.S.O. S. 4404	0 (0				
a) ☐ All b) ☐ Some * c) ☐ None of:	only under 35 U.S.C. § 119(a)-(d) or (f).				
 Certified copies of the priority documents have 	ave been received	•				
2. Certified copies of the priority documents ha	ave been received in Application	M-				
3. Copies of the certified copies of the priority	documents have been re	NO.				
application from the international Bureau (P	CT Rule 17 2/2\\	in this National Stage				
* See the attached detailed Office action for a list of the	16 certified copies not received					
	to the series included.					
ttachment(s)	•					
One of References Cited (PTO-892)						
Notice of Draftsperson's Patent Drawing Review (PTO-948)	 Interview Summary (PT Paper No(s)/Mail Date. 	O-413)				
Information Disclosure Statement(s) (PTO/SB/08)	 Notice of Informal Pater 	nt Application				
Paper No(s)/Mail Date Patent and Trademark Office	6) Other:					
OL-326 (Rev. 08-06) Office Action:	Summary Dod of	Paner No Mail Date 20074049				

Application/Control Number: 10/390,511
Art Unit: 1618

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 37-41 and 45-49, drawn to an anhydrous personal lubricant composition, classified in class 424, subclass 488.
- II. Claims 42-44, drawn to a method of providing personal lubricationto a human's vaginal mucosa, classified in class 514, subclass 57.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used as a lotion for back massages.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: viscosity of 1,000cps to about 7,000cps, and 60,000cps to about 500,000cps.

Application/Control Number: 10/390,511

Art Unit: 1618

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The species are independent or distinct because these are different ranges of viscosity.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

Application/Control Number: 10/390,511

Art Unit: 1618

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/390,511

Art Unit: 1618

Page 5

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD Art Unit 1618

> MICHAEL G. HARTLEY SUPERVISORY PATENT EXAMINER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ahmad et al. Serial No. : 10/390,511

Filed : March 17, 2003

Title : WARMING AND NONIRRITATING LUBRICANT

COMPOSITIONS AND METHOD OF COMPARING IRRITATION
Art Unit 1618

Art Unit : 1618
Examiner : Jake Minh Vu

I hereby certify that this correspondence is being filed via
The Office electronic filling system in accordance with 37 CFR 1.6(a)(4) on
November 5, 2007

(Date of Deposit)

Andrea L. Colby, Reg. No. 30,194
(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

November 5, 2007 (Date of Signature)

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir-

This Response to Restriction Requirement is respectfully submitted in response to the Office Action of October 12, 2007. It is timely in view of the one-month shortened statutory period for response.

Status of the Claims is reflected on page 2 of this paper.

Remarks are reflected on page 6 of this paper.

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the captioned application:

Claims 1-36 (Canceled)

- 37. (New) A substantially anhydrous personal lubricant composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohol, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
- 38. (New) A substantially anhydrous personal lubricant composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid.
- 39. (New) A substantially anhydrous personal lubricant composition consisting essentially of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.
- (New) A composition according to claim 37 wherein said composition has a viscosity from about 1,000 cps to about 7,000 cps.
- (New) A composition according to claim 37 wherein said composition has a viscosity from about 60,000 cps to about 500,000.
- (New) A method according to claim 20 wherein said composition further comprises a preservative.
- 43. (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition consisting essentially of from about 75% to about 99% by weight of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, from about 0.1% to about 4% by weight of hydroxypropylcellulose and from about 0.1% to about 1% by weight of lactic acid, said composition conveying a feeling of warmth upon application.
- (New) A method of providing personal lubrication to a human's vaginal mucosa comprising applying to the vaginal mucosa a substantially anhydrous composition

consisting essentially of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.

- 45. (New) A substantially anhydrous personal lubricant composition consisting of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof, hydroxypropylcellulose and lactic acid.
- 46. (New) A substantially anhydrous personal lubricant composition consisting of polyhydric alcohols selected from the group consisting of propylene glycol, polyethylene glycol and a mixture thereof and hydroxypropyleellulose.
- (New) A composition according to claim 46 wherein said composition further comprises honey.
- (New) A composition according to claim 46 wherein said polyhydric alcohols present are propylene glycol and polyethylene glycol.
- 49. (New) A composition according to claim 48 wherein said polyhydric alcohols are present in the amount of from about 75% to about 99% by weight and said hydroxypropylcellulose is present in the amount of from about 0.1% to about 4% by weight of the composition.

REMARKS

This Response is respectfully submitted in response to the Office Action of October 12, 2007. The Office Action required restriction to one of the following inventions under 35 U.S.C. 121-

- Claims 37-41 and 45-49, drawn to an anhydrous personal lubricant composition, classified in class 424, subclass 488.
- II. Claims 42-44, drawn to a method of providing personal lubrication to a human's vaginal mucosa, classified in class 514, subclass 57.

The Office Action noted that:

Inventions I and II are related as product and process of use...In the instant case the product can be used as a lotion for back massages.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search..., restriction for examination purposes as indicated is proper. [Office Action, p. 2]

The Office Action further indicates that an election of species is required between "the following patentably distinct species: viscosity of 10,000cps to about 7,000cps, and 60,000cps to about 500,000cps" [Office Action, p. 2]. Applicants respectfully respond to the restriction requirement and species election as follows.

Applicants respectfully provisionally elect the inventions of Group I, with traverse. Applicants respectfully submit that the searching of these two Groups of claims should not entail a burden upon the Patent and Trademark Office. Applicants therefore respectfully request reconsideration of the restriction requirement.

Applicants, having provisionally elected the claims of Group I, respectfully elect the species defined as follows: 1,000cps to about 7,000cps.. Applicants believe that Claims 37-41 and 45-49 read thereon.

An early allowance is earnestly solicited.

Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby Attorney for Applicants Reg. No. 30,194

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, New Jersey 08933-7003 (732) 524-2792 November 5, 2007

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1459 Alexadrin, Virginia 22313-1450

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,353 10/30/2003		Nawaz Ahmad .	PPC-834-CIP-4	7581
27777 1590 03/20/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSVICK, N. 08933-7003		Α	EXAM ANTHONY, JO ART UNIT	
			1714	PAPER NUMBER
SHORTENED STATUTORY	PERIOD OF RESPONSE	MAIL DATE	DELIVERY	MODE
3 MON	THS	03/20/2007		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.		th/
		Applicant(s)	
Office Action Summary	10/697,353 Examiner	AHMAD ET AL.	
	Joseph D. Anthony	Art Unit	
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the	1714	14
A SHORTENED STATUTIORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA Estimation of time ray be realised and the provisions of 3°CFR 1.13 after 5°K (6) MONTHS from the maintained and provided and the state of the st	6(a). In no event, however, may a reply be tin	N. nely filed	
Status			
1) Responsive to communication(s) filed on 18 Dec	cember 2006		
2a) This action is FINAL. 2b) This a	action is non-final		
Since this application is in condition for allowance	e except for formal matters, are	secution as to the	morito is
closed in accordance with the practice under Ex	parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.	ments is
Disposition of Claims			
4) ⊠ Claim(s) 1-16 and 18-26 is/are pending in the application. 4a) Of the above claim(s) 1-16,18,19 and 24 is/are withdrawn from consideration. 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 20-23 and 25-26 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or election requirement.			
Application Papers	To a series of the series of t		
 The specification is objected to by the Examiner. 			
10) The drawing(s) filed on is/are: a) accept	ed or h) Clobiostad to to it.		
replicant may not request that any objection to the drag	wing(s) he hold in chause		
			1.4044.0
11) The oath or declaration is objected to by the Exam	iner. Note the attached Office A	tion or form PTO	-1.121(a). -152
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign price a) All b) Some * c) None of:) or (f).	
1. Certified copies of the priority documents ha	ve been received.		
2. Certified copies of the priority documents ha	ve been received in Application	No	
 Copies of the certified copies of the priority of application from the International Bureau (PC) 	locuments have been received in	n this National Sta	ige
* See the attached detailed Office action for a list of th	P Rule 17.2(a)).		*
	o connect copies not received.		
Attachment(s)			
1) Notice of References Cited (PTO-892)	4) Interview Summary (PTC	1440	
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Date.		
Paper No(s)Mail Date	5) Notice of Informal Patent 6) Other:	Application	
. Patent and Trademark Office OL-326 (Rev. 08-06) Office Action S	ummary Part of F		

Application/Control Number: 10/697,353
Art Unit: 1714

FINAL REJECTION

Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United .
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the Invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: Application/Control Number: 10/697,353

Art Unit: 1714

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 20-23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative as being rejected under 35 U.S.C. 103(a) as being obvious over applicant's supplied English Language Translation of Akiyama et al. JP Application Publication Number 2-311408 or applicant's supplied English Language Translation of Osamu et al. JP Publication Number 2001-335429 or applicant's supplied English Language Translation of Carreras et al. ES 2,074,030 or the English Language Abstract of WO 01/64176.

Akiyama et al., Osamu et al., Carreras et al. and WO all directly teach anhydrous or substantially anhydrous gel or gel-like therapeutic topical compositions for use on the human body such as the skin. The said therapeutic topical compositions comprise at least one polyol, such as propylene glycol, polyethylene glycol, glycerin or the like. The thickening agent can be hydroxyethyl cellulose or the like. Additional adjuvants well known in be used in therapeutic topical compositions, such as antimicrobial agents, anti-inflammatory agents, anti-septics, pH regulators, etc., can optionally be added to said compositions. All said therapeutic topical compositions are disclosed to generate heat of solution when they are brought in contact with moisture such as water. See at least the abstracts, examples and claims of each reference. Applicant's claims are deemed to be anticipated over the said disclosures and examples of each individual reference.

Application/Control Number: 10/697,353

Art Unit: 1714

invention also relates to methods of using such compositions for lubrication, administration of active ingredients and for preventing or treating dysmenorrhea. Applicant's claims are deemed to be anticipated over the examples of the patent, see abstract, examples and claims. Applicant's attention is drawn to the fact that applicant's specification in Example 9 directly teaches compositions 1-9 that are asserted by applicant to be composition of the invention, as such they must be compositions that meet the limitation of: "wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a Energy Release index of at least about 11 mJ/mg". Since the Ahmad et al patent directly teaches the same compositions 1-9, see columns 11-12, the Ahmad et al compositions must inherently meet applicant's claimed performance limitations.

NOTE: the examiner is well aware that applicant's pending application is a CIP application of S.N. 10/137,509 Now U.S. Patent Number 7,005,408. The new matter in all of applicant's claims is deemed to be the limitation of: "wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a Energy Release index of at least about 11 mJ/mg". As such, the effective filling date of applicant's pending claims is 10/30/2003 which is the actual filling date of the present application. Since the filling date of U.S. Patent Number 7,005,408 is 05/01/2002, the patent qualifies as prior-art under 35 U.S.C. 102(e).

In the alternative, applicant's claims may be said to "differ" from Ahmad et al. in that the patent does not directly state in writing applicant's claimed limitation of: "wherein said composition increases in temperature by at least about 5°C upon

Application/Control Number: 10/697,353 Art Unit: 1714

exposure to moisture and which has a Energy Release Index of at least about 11 mJ/mg. Although, applicant's said limitation is not directly stated in writing, it is nevertheless deemed to be obvious to one having ordinary skill in the art to make compositions that meet applicant's claimed performance requirements, using the disclosure of the patent as motivation because: 1) the patent teaches therapeutic topical compositions that contain the same components as applicant's compositions in approximately the same concentration ranges, 2) the patent teaches that the therapeutic topical compositions generate heat of solution when brought in contact with moisture, 3) the patent teaches that the use of there therapeutic topical compositions is for application to human skin and/or mucosal surfaces which by its very nature would require certain performance characteristic and limits to the amount of heat generated., and 4) applicant have set forth no showing of any criticality and/or superior and unobvious results for their claimed performance limitations.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See Miller v. Eagle Mig. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Application/Control Number: 10/697,353 Art Unit: 1714

- 6. Claims 20-23 and 25-26 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15, 19-22 and 24 of copending Application No. 10/696,939. This is a <u>provisional</u> double patenting rejection since the conflicting claims have not in fact been patented.
- 7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1993); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 20-23 and 25-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 15, and 19-24 of U.S. Patent No. 7,005,408. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is massive overlap in the claimed subject matter.

Application/Control Number: 10/697,353

Art Unit: 1714

Claims 20-23 and 25-26 are provisionally rejected on the ground of nonstatutory 9. obviousness-type double patenting as being unpatentable over claims 13-18 of copending Application No. 10/697,383; as being unpatentable over claims 24-28 of copending Application No.10/389,871; as being unpatentable over claims 20-35 of copending Application No. 10/390,511; and as being unpatentable over claims 15 and 19-23 of copending Application No. 11/299,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims in the present application are deemed to be a subset of the pending claims in said other pending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

10. Applicant's arguments filed 12/18/06 with the amendment have been fully considered but are not persuasive to put the application in condition for allowance for the reasons set forth above. Additional examiner comments are set forth next.

The examiner has dropped the previously made prior-art rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over applicant's supplied English Language Translation of Akiyama et al. JP Application Publication Number 2-311408 or applicant's supplied English Language Translation of Osamu et al. JP Publication Number 2001-335429 or applicant's supplied English Language Translation of Carreras et al. ES 2,074,030 or the English Language Abstract of WO 01/64176. The reasons for

Application/Control Number: 10/697,353
Art Unit: 1714

this drop is that the examiner has now concluded that there is insufficient support within these references to reject applicant's claimed process of treating dysmenorrheal.

Applicant's amendment of "during intimate activities" incorporated into independent claims 21-23 and new claim 26, is not deemed to overcome the prior-art rejections made over applicant's supplied English Language Translation of Akiyama et al. JP Application Publication Number 2-311408 or applicant's supplied English Language Translation of Osamu et al. JP Publication Number 2001-335429 or applicant's supplied English Language Translation of Carreras et al. ES 2,074,030 or the English Language Abstract of WO 01/64176, because: 1) the metes and bounds of the phrase "during intimate activities" is completely undefined and 2) according to applicant's own disclosure, applying the composition directly to skin can be considered to be a form of intimate activities.

Finally, applicant's assertion that the applied Ahmad et al. U.S. Patent Number 7,005,408 should be dropped because it is not to another is totally rejected by the examiner because it such is clearly a false statement. Applicant's claimed application has 6 listed inventors whereas Ahmad et al. U.S. Patent Number 7,005,408 has only 3 listed inventors of which only Nawaz Ahmad is a common inventor. As such, Ahmad et al. U.S. Patent Number 7,005,408, clearly has a different inventive entity than applicant's claimed application.

Conclusion

 THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). Application/Control Number: 10/697,353
Art Unit: 1714

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner Information

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Joseph D. Anthony whose telephone number is (571) 272-1117. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The centralized FAX machine number is (571) 273-8300. All other papers received by FAX will be treated as Official communications and cannot be immediately handled by the Examiner.

Joseph D. Anthony Primary Patent Examiner Art Unit 1714

3/15/07





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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/697,353	10/30/2003	Nawaz Ahmad	PPC-834-CIP-4	7581
PHILIP S. JOH			EXAMI	NER
JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ANTHONY, JO	SEPH DAVID
		003	ART UNIT	PAPER NUMBER
			1714	
			MAIL DATE	DELIVERY MODE
			10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ł		Application No.	I A
	Examiner-Initiated Interview Summary	10/697,353	Applicant(s) AHMAD ET AL.
-	on and a second	Examiner	Art Unit
-		Joseph D. Anthony	1714
	All Participants:	Status of Application:	
	(1) <u>Joseph D. Anthony</u> .	(3)	
1	(2) Angela Randel (assistant to Andrea L. Colby).	(4)	
	Date of Interview: 28 September 2007	Time:	
	Type of Interview: ☐ Telephonic ☐ Video Conference ☐ Personal (Copy given to: ☐ Applicant ☐ Applicant ☐ Shribit Shown or Demonstrated: ☐ Yes If Yes, provide a brief description:	e's representative)	
	Part I.		
	Rejection(s) discussed:		
	Claims discussed:		
F	Prior art documents discussed:		
F	Part II.		
A	SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL ds. Randel said case has been let gone abandoned.	. NATURE OF WHAT WAS D	ISCUSSED:
P	art III.		
	It is not necessary for applicant to provide a separate recordirectly resulted in the allowance of the application. The exit of the interview in the Notice of Allowability. It is not necessary for applicant to provide a separate recordid net result in resolution of all seekes. A brief summary by	aninei wiii piovide a written s	summary of the substance
,	Ino There les	dhelm	
(Ex	aminer/SPE Signature) (Applicant/Appli	cant's Representative Signatu	Ire - if appropriate)
J.S. P	alent and Trademark Office		is appropriate)

Application No. Applicant(s) 10/697,353 Examiner Notice of Abandonment AHMAD ET AL Art Unit Joseph D. Anthony

1714

-- The MAILING DATE of this com-

This application is abandoned in view of:
Applicant's failure to timely file a proper reply to the Office letter mailed on 20 March 2007. (a) A reply was received on(with a Certificate of Malling or Transmission dated), which is after the expiration of the period for reply (including a total extension of time ofmonth(s)) which expired on
(b) A proposed reply was received on but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection. (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
(c) ☐ A reply was received onbut it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
(d) ⊠ No reply has been received.
 Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
(a) The issue fee and publication fee, if applicable, was received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-35).
(b) ☐ The submitted fee of \$ is Insufficient. A balance of \$ is due.
The issue fee required by 37 CFR 1.18 is \$ The publication fee, if required by 37 CFR 1.18(d), is \$
(c) The issue fee and publication fee, if applicable, has not been received.
Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 (a) Proposed corrected drawings were received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the period for reply.
(b) \(\square\) No corrected drawings have been received.
☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filling of a continuing application.
☐ The decision by the Board of Patent Appeals and Interference rendered on and because the period for seeking court review of the decision has expired and there are no allowed claims.
☐ The reason(s) below:
forget a butter
Joseph D. Anthony Primary Examiner 9/25/07 At Unit 1714
illions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181 should be promptly find to

minimize any negative effects on patent term.
U.S. Palent and Trademark Office
PTOL-1432 (Rev. 04-01)

(19) Japanese Patent Office (JP)

(12) Official Gazette of Unexamined Patent Applications (A)

(11) Patent Application Publication Number: 2-311408

(43) Patent Application Publication Date: December 27, 1990

Identification Code

(51) Int. Cl.5 A 61 K

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8413-4C

Request for Examination: Not Yet Requested

Number of Claims: 2

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(Total of 5 Pages)

Internal File Nos.

(54) Title of the Invention: Gelatinous Composition for Skin

(21) Application Number:

1-133763

(22) Application Date:

May 25, 1989

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(74) Agent:

Yoshihiro Kıyohara, Patent Attorney

Specification

1. Title of the Invention

Gelatinous Composition for Skin

2. Claims

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- (1) A gelatinous compound for skin, wherein an anionic polymer compound and a water-soluble non-ionic polymer compound are compounded in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater.
- (2) The gelatinous compound for skin described in claim 1, wherein the compositional ratio of the solvent is 99.7 wt% or less of the entire composition.

Detailed Description of the Invention

(Industrial Field of Application)

The present invention relates to a gelatinous compound for skin. The purpose of the present invention is to provide a gelatinous composition for skin that can be used as a pack or massage agent. When applied using the fingers or palm of the hand, it goes on without running and feels good on the skin. When applied as a pack, the heat from the hydration reaction with the water content of the skin generates heat. When the gelatinous compound for skin is used in a massage, the force of the massage is tangibly transferred to the skin without excessive peeling of the corneum due to friction.

(Prior Art)

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Skin generally comprises the stratum corneum consisting of hard protein, the epidermis covering the stratum comeum, tough fiber tissue and elastic subcutaneous tissue. This is extremely important to the functioning of the human body.

The skin performs protective, temperature-regulating, sense, respiratory, secretive and absorptive functions. The skin also gradually changes state as the body matures from childhood to the prime of life.

As skin ages, it begins to wither, lose elasticity and appear noticeably more wrinkled. A balanced diet and psychological stability are very important to the skin.

Another means of preserving the health of the skin is massage.

Massage stimulates the surface of the skin, which gets the blood flowing, increases metabolism, and activates skin tissue. In order to prevent excessive peeling of the corneum due to friction during massage, oily creams or lotions are used whose main component is a hydrocarbon-based oil.

However, the massage effect is not as good when one of these massage creams or massage lotions is used because insufficient load is applied to the skin.

Also, these massage creams and massage oils do not sufficiently rinse off because their main component is an oil. After use, the skin remains oily to the touch.

A pack temporarily raises skin temperature, increases blood flow and boosts the metabolism of skin tissue, and there is interest in developing a good massage agent that combines these functions.

(Means of Solving the Problem)

The present invention is a gelatinous compound for skin, wherein an anionic polymer compound and a water-soluble non-ionic polymer compound are compounded in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater. This is successful at eliminating the shortcomings of the prior art.

(Composition of the Invention)

The main component in the solvent used in the present invention is a polyhydric alcohol such as propylene glycol, glycerin, diglycerin and dipropylene glycol.

These polyhydric alcohols feel warm to the touch when used because of heat from the hydration reaction with the water content of the skin.

The concentration of polyhydric alcohol should range between 80 and 100 wt%.

If there is less than 80 wt% in the solvent when the solvent is compounded to prepare the gelatinous composition for skin, polyhydric alcohol reacts with the water or lower alcohol used as a diluent in the solvent and heat is generated from the hydration reaction. When applied to the skin, there is no hydration reaction heat and a heat effect is not experienced.

The compositional ratio of the solvent should be 99.7 wt% or less of the entire composition.

If the amount of solvent exceeds 99.7 wt% of the entire composition, the composition does not gel properly during compounding.

In addition to the polyhydric alcohol, the solvent in the present invention can contain 0 to 20 wt% water, lower alcohol such as ethanol, isopropyl alcohol or propyl alcohol, or an organic solvent such as ethyl carbitol, ethyl cellosolve, chloroform, isopropyl myristate or isopropyl palmitate.

The anionic polymer compound used in the present invention can be polyacrylic acid, carboxyethyl cellulose or carboxyvinyl polymer.

Because the non-ionic polymer compound used in the present invention is the gelling agent, a carboxyvinyl polymer is preferred.

This is because a gel produced by a carboxyvinyl polymer has many advantages. It is non-sticky, resists microbes and moids, a small amount provides high viscosity, and it is thixotropic. It is also highly stable and can be used in a wide variety of solvents containing water and different alcohols and polyhydric alcohols.

The amount of anionic polymer compound used in the present invention should be 0.1 to 10 wt% of the overall composition.

If less than 0.1 wt% is used, gel formation is poor. If more than 10 wt% is used, solubility and dispersability decline and the composition becomes difficult to prepare. The gel viscosity is also too high and the composition does not feel good to the touch.

After the anionic polymer composition has been dissolved and dispersed in the solvent, an appropriate neutralizer is added.

A neutralizer is added to neutralize the anionic polymer composition and provide a more viscous gel. This can be an inorganic alkali compound or an organic alkali compound.

Specific examples of inorganic alkali compounds include sodium hydroxide, calcium hydroxide and potassium hydroxide. Specific examples of organic alkali compounds include monoethanol amine, diethanol amine, triethanol amine, aminomethyl propanol and aminomethyl propanediol.

The amount of neutralizer added should be enough to cause the anionic polymer compound to gel. The actual amount depends on the type of anionic polymer compound and the amount of anionic polymer compound used.

The water-soluble non-ionic polymer compound used in the present invention is preferably hydroxyethyl cellulose, xanthan gurn, polyvinyl alcohol or polyvinyl pyrrolidone. Among these, hydroxyethyl cellulose and polyvinyl pyrrolidone are recommended.

By compounding the water-soluble non-ionic polymer compound with the anionic polymer composition in a solvent whose main component is a polyhydric alcohol, sufficient load can be applied during a massage to the skin without causing excessive peeling of the comeum due to friction.

The amount of water-soluble non-ionic polymer compound used in the present invention should be 0.1 to 10 wt% of the overall composition. If less than 0.1 wt% is used, the massage effect of the resulting gelatinous composition for skin is not sufficient. If more than 10 wt% is used, it becomes difficult to stir because of solubility. Therefore, less than 10 wt% is used.

In the present invention, additives such as fragrance and pigment are added in the usual way. Polyethylene particles can be added to improve the feel of the composition on the skin.

The following is a clearer explanation of the effect of the present invention with reference to working examples of the present invention.

(Working Examples 1-7 and Comparative Examples 1-3)

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The gelatinous compositions for skin in Working Examples 1-7 and Comparative Examples 1-3 were prepared as shown in Table 1 through Table 4.

The gelling effect, heat effect and massage effect of these gelatinous compositions for skin were then tested in the following manner.

After applying 5 g of the compositions to the inside skin of the upper arm on 10 test subjects (19 to 30 years old) and allowing them to stand for several minutes, the arms were massaged for several minutes more. The subjects were then interviewed and numeric values were assigned to the various effects.

Average values were then calculated.

The evaluation process used a five-value scale: -2, -1, 0, +1, +2.

In the final evaluation, the averages were assigned symbols: a result between -1 and -2 was assigned x (poor), between 0 and -1 was assigned Δ

(somewhat poor), between 0 and +1 was assigned O (good), and between 1 and 2 was assigned **O** (very good).

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Table 1 (Working Example 1)

Carboxyvinyl Polymer	0.4
Polyvinyl Pyrrolidone	3.0
Glycerin	90.0
Polyoxyethylene (20) Polyoxypropylene (6) Decyltetradecylether	0.2
Fragrance	0.2
Methyl p-Aminobenzoic Acid	0.2
Triethanol Amine	0.4
Pigment	Trace
Purified Water	Amount
	Remainder
Total	100.0

Table 2 (Working Example 2)

Carboxyvinyl Polymer	0.2
Polyvinyl Pyrrolidone	5.0
Diglycerin	40.0
Propylene Glycol	40.0
Polyoxyethylene (60) Hardened Castor Oil	0.1
Fragrance	0.1
Methyl p-Aminobenzoic Acid	0.2
Triethanol Amine	0.2
Pigment	Trace
Polyethylene Particles	Amount
Purified Water	5.0
	Remainder
Total	
Total	100.0

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Table 3

	Working		Comparative
	Examples		Example
	3	4	1
Glycerin	90.0	90.0	90.0
Diglycerin	-		-
Propylene Glycol	-	-	-
Polypropylene	1.0	0.1	
Pyrrolidone	1		
Hydroxyethyl Cellulose	-	-	-
Carboxyvinyl Polymer	1.0	1.0	1.0
Triethanol Amine	1.0	1.0	1.0
Purified Water	Remainder	Remainder	Remainder

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Table 4

	Working		Comparative
	Examples		Example
	5	6	2
Glycerin	-	-	
Diglycerin	-	-	-
Propylene Glycol	80.0	80.0	80.0
Polypropylene Pyrrolidone	-	-	-
Hydroxyethyl Cellulose	1.0	1.0	1.0
Carboxyvinyl Polymer	0.5	0.1	-
Triethanol Amine	0.5	0.1	
Purified Water	Remainder	Remainder	Remainder

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Table 5

	Working		Comparative
	Examples		Example
	7	8	3
Glycerin	-	-	-
Diglycerin	99.7	80.0	70.0
Propylene Glycol	-	-	-
Polypropylene	0.1	0.1	0.1
Pyrrolidone	1		
Hydroxyethyl Cellulose	-	-	-
Carboxyvinyl Polymer	0.1	0.1	0.1
Triethanol Amine	0.1	0.1	0.1
Purified Water	Remainder	Remainder	Remainder

(Blank Space)

Table 6

	ł	Working Examples								Comparative Examples		
	1	2	3	4	5	6	7	8	1	2	[3	
Gel	0	0	0	0	0	0	0	0	0	×	0	
Heat Action	0	0	0	0	0	0	0	0	0	0	×	
Massage	0	0	0	0	0	0	0	0	Δ	Δ	Δ	

(Effect of the Invention)

As described above, the present invention is a gelatinous compound for skin, wherein an anionic polymer compound and a water-soluble non-ionic polymer compound are compounded in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater. As a result, it has the following effects.

When applied using the fingers or palm of a hand after pouring it out from the mouth of a bottle, it covers the skin without becoming runny.

When covering the skin, it feels good and not greasy. The heat generated by the hydration reaction with the water content of the skin makes the skin warm.

During the massage, the force of the massage is transferred tangibly to the skin without causing excess peeling of the corneum due to friction.

Agent Yoshihiro Kıyohara, Patent Attorney [seal affixed]

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